

## **REMARKS**

### **FORMAL MATTERS:**

Claims 31, 33, 35-43 and 45-56 are pending after entry of the amendments set forth herein.

Claims 1-30, 32, 34 and 44 are canceled without prejudice.

Claims 31, 35, 36, 41, 51, 55 and 56 are amended.

The claim amendments include limitations contained within previously pending now canceled dependent claims.

Claim 31 incorporates the limitation contained within previously pending now canceled claim 34. Specifically, claim 31 is amended to indicate that the actuator mechanism is an actuator lever.

In view of the amendment to claim 31, claim 34 was canceled and claim 35 was amended to refer to the actuator mechanism as being an actuator lever.

Claim 41 has been amended to more specifically define the break-off tip. The amendments to claim 41 are supported within previously pending now canceled claim 44.

The amendments to claim 56 are supported within previously pending now canceled claim 44.

The amendments to claims 36, 51 and 55 are formal in nature and made in view of the cancellation of claims 34 and 44.

No new matter is added.

## **ARGUMENTS RESPONDING TO REJECTIONS OF FINAL OFFICE ACTION OF FEBRUARY 2, 2010**

### **REJECTIONS UNDER §102 – CASTELLANO ET AL.**

Claims 31 and 33-56 were rejected under 35 U.S.C. §102 as anticipated by Castellano et al. The rejection is traversed as applied and as it might be applied to the presently pending claims.

Claim 31 has been amended to indicate that the actuator mechanism is “an actuator lever.” This lever is configured such that it “moves the safety mechanism from its first configuration to its second configuration.” There is no such lever disclosed within Castellano. In order for the claims to be anticipated by a reference each of the components claimed must be shown within the reference and Castellano et al. do not show an actuator lever of the type claimed in amended claim 31.

Claims 41 and 56 have been amended with respect to the break-off tip. The rejection has referred to the removable and replaceable protective cap 5046 as meeting the limitations of the claimed “break-off tip.” However, it is clear that the protective cap 5046 of Castellano et al. is **removable and replaceable**. Claims 41 and 56 have been amended to specifically indicate that the break-off tip is configured “such that breaking off the break-off tip **irreversibly exposes** an actuator for the safety mechanism.” The removable protective cap 5046 of Castellano is not broken off, but is removed in a way such that it can be replaced. Accordingly, the removable cap 5046 is Castellano et al. is not configured such that when it is broken off it “**irreversibly exposes an actuator**” as claimed within amended claims 41 and 56.

Claims 31, 41 and 56 are the only independent claims. Because each limitation of the independent claims 31, 41 and 56 are not taught within the Castellano et al., the reference does not anticipate these claims. Accordingly, the 35 U.S.C. 102 rejection should be reconsidered and withdrawn.

#### **REJECTIONS UNDER §102 – HAAR ET AL.**

Claims 31 and 33-56 were rejected under 35 U.S.C. §102 as anticipated by published U.S. Patent 2001/0031945 to Haar et al. The rejection is traversed as applied and as it might be applied to the presently pending claims.

In support of the rejection reference is made to Figures 4 and 5 showing a “button.” However, the Haar et al. reference does not refer to the word “button.” Notwithstanding this position claim 31 has been amended to refer to the actuator as an “actuator lever.” More specifically, the claimed actuator lever moves the safety mechanism from its first configuration to a second configuration. No such lever is taught within Haar et al.

The rejection has referred to the indentations and concave depressions on the push rod 38 of Haar et al. However, these components do not make up a “safety mechanism” of the type claimed in claim 31, wherein an actuator lever moves the safety mechanism from a first configuration to a second configuration.

With respect to claims 41 and 56, these claims have been amended to refer to the “break-off tip” more specifically by indicating that break-off tip is “configured such that breaking off the break-off tip **irreversibly exposes an actuator for the safety mechanism.**” The removable cap 44 of Haar et al. is clearly replaceable. It is not clear if the tear-off closing tab 22 of Haar et al. is replaceable. However,

neither component is configured in such a way that after they are removed they expose any safety mechanism. Accordingly, Haar et al. does not anticipate the claimed invention within the meaning of 35 U.S.C. §102 and the rejection should be withdrawn.

#### **UNOBVIOUSNESS OF THE CLAIMED INVENTION**

The above explanation clearly shows that neither Castellano et al. or Haar et al. anticipate the claimed invention particularly as the claims are currently amended. It is also applicants' position that the claimed invention is not obvious in view of either of these references.

Needle-free injector devices require special consideration regarding the inclusion of safety mechanisms to prevent accidental firing of the device and also require special considerations with respect to showing whether the device has been used. It will be appreciated that needle-delivery devices also require safety precautions in order to prevent needle pricks. However, these precautions are generally apparent to the user, e.g. avoid getting picked with the sharp needle point. Accordingly, the precautions taken are unrelated to those which need to be taken in connection with the needle-free system where there is no sharp point, and the need for safety precautions are far less apparent. With a syringe system which uses a needle it is always clear when the needle is exposed and can prick an individual, and it is also clear when the device has been used. Neither is true with respect to a needle-free device. Applicants' system makes it possible to: (1) prevent accidental firing; and (2) show a user when a device has already been used.

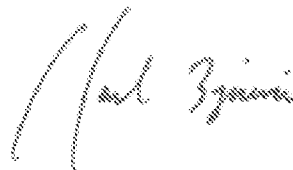
The "actuator lever" as claimed within amended claim 31 is used in order to move the safety mechanism from a first configuration to a second configuration. Until the safety mechanism is moved to the second configuration the trigger mechanism cannot actuate the drive mechanism. Neither Castellano et al. or Haar et al. disclose such an actuator lever. With respect to claims 41 and 56 applicants claim the break-off tip. This break-off tip is configured such that after breaking off the break-off tip the actuator is irreversibly exposed. The tip cannot be replaced once it is broken off, thereby definitively letting the user know that the device has been used. Because the tip cannot be replaced it is quite different from the replaceable protective cap 5046 of Castellano et al. or the removable cap 44 of Haar et al. Still further, the break-off tip is configured to expose an actuator mechanism and no removable or break-off component of any type within either Castellano et al. or Haar et al. is broken off to expose an actuator mechanism.

**CONCLUSION**

Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number ZGNX-115.

Respectfully submitted,  
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By: \_\_\_\_\_

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